The following corrections or additions to the January 2006 list were published in the Federal Register in July 2006.

New Approvals

ANADA Number: 200-391

Pioneer Product:	039-792
Trade Name:	Griseofulvin Powder
Ingredients:	Griseofulvin
Sponsor:	IVX Animal Health, Inc.
Approval Date:	June 1, 2006
Status:	Prescription only
Route:	Oral
Species:	Horses
Drug Form:	Powder
Concentration:	2.5 grams griseofulvin per 15 gram container
Indications:	For the treatment of ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum.*

21CFR 520.1100

ANADA Number: 200-305

Pioneer Product:	130-435
Trade Name:	Oxytetracycline Hydrochloride Soluble Powder
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Vétoquinol N.-A., Inc.
Approval Date:	June 2, 2006
Status:	Over-the-counter
Route:	Oral (drinking water)
Species:	Chickens, turkeys, and swine
Drug Form:	Powder
Concentration:	102.4 grams of oxyteteracycline hydrochloride per 280 grams of powder
Indications:	For the treatment or control of bacterial diseases in chickens, turkeys, and swine caused by organisms susceptible to oxytetracycline.
Tolerance:	21 CFR 556.500 Oxytetracycline: The tolerances established for tetracycline residues in the uncooked edible tissue of turkeys, chickens, and swine are the following: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney, 0.3 ppm in milk.
Withdrawal:	Zero days in turkeys, chickens, and swine.

21CFR 520.1660(d)

ANADA Number: 200-283

Pioneer Product:	140-896
Trade Name:	Vetro-Max®
Ingredients:	Gentamicin sulfate, betamethasone valerate, clotimazole
Sponsor:	Altana, Inc.
Approval Date:	June 1, 2006
Status:	Prescription only
Route:	Topical
Species:	Dogs
Drug Form:	Ointment
Concentration:	Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams gentamicin base, betamethasone valerate equivalent to 1 milligrams betamethasone, and 10 milligrams clotrimazole.
Indications:	For the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*), and/or bacteria susceptible to gentamicin.

21CFR 524.1044g

ANADA Number: 200-430

Pioneer Product:	138-992
Trade Name:	Heifermax™ 500 Liquid Premix, Bovatec®, Tylan®
Ingredients:	Melengestrol acetate, lasalocid sodium, tylosin phosphate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	June 1, 2006
Status:	Over-the-counter
Route:	Oral
Species:	Beef cattle; heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles for use in combination for the manufacture of three-way Type C medicated feeds.
Concentration:	Melengesterol acetate - 500 milligrams melengestrol acetate activity per pound of Liquid Type A medicated article. Lasalocid sodium - 68, 91, 150, or 227 grams of activity per pound of Type A medicated article Tylosin phosphate - 10, 40, or 100 grams of tylosin phosphate activity per pound of Type A medicated article.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in heifers being fed in confinement for slaughter.
Tolerance:	21 CFR 556.380 Melengestrol Acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat, of cattle. 21 CFR 556.347 Lasalocid: A tolerance of 0.7 part per million is established for residues for the parent compound in the liver of cattle. 21 CFR 556.740 Tylosin: A tolerance of 0.2 part per million is established for negligible residue in uncooked fat, muscle, liver, and kidney in cattle.
Withdrawal:	Zero days

21CFR 558.342

ANADA Number: 200-390

Pioneer Product:	134-314
Trade Name:	Ivermectin Paste 1.87 %
Ingredients:	Ivermectin
Sponsor:	Med-Pharmex, Inc.
Approval Date:	June 20, 2006
Status:	Over-the-counter
Route:	Oral
Species:	Horses, not intended for human consumption
Drug Form:	Paste
Concentration:	1.87 %
Indications:	For treatment and control of the following parasites: **Large Strongyles** (adults) – *Strongylus vulgaris* (also early forms in blood vessels), *S .edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp. including *T. Brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum;* **Small Strongyles** (adults, including those resistant to some benzimidizole compounds) – *Coronocyclus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*; *Cyanthostomum* spp. including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus* and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi'* **Ascarids** (adults and third- and fourth-stage larvae) – *Parascaris equorum;* **Hairworms** (adults) – *Trichostrongylus axei;* **Large-mouth Stomach Worms** (adults) – *Habronema muscae;* **Bots** (oral and gastric stages) – *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis;* **Lungworms** (adults and fourth-stage larvae) – *Dictyocaulus arnfieldi;* **Intestinal Threadworms** (adults) – *Strongyloides westeri;* **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

21CFR 520.1192

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 100-616

Trade Name: Horseshoer's Secret Thrush Treatment Aid (formerly Thrush-XX)
Ingredients: Copper naphthenate
Sponsor: Farnam Companies, Inc.
Approval Date: May 30, 2006

This application provides for revised food safety warning on labeling.

21CFR 524.463

NADA Number: 112-048

Trade Name: Hylartin® V
Ingredients: Hyaluronate sodium
Sponsor: Pharmacia & Upjohn Co.
Approval Date: May 30, 2006

This application provides for revised food safety warning on labeling.

21CFR 522.2245

NADA Number: 141-209

Trade Name: Excede® Sterile Suspension
Ingredients: Ceftiofur crystalline free acid
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for use of ceftiofur crystalline free acid suspension via a new injection site in beef and nonlactating dairy cattle, for use in lactating dairy cattle for the treatment of respiratory disease, and for the establishment of a 13-day pre-slaughter withdrawal period in cattle. FDA is also amending the regulations to revise the tolerance for residues of ceftiofur in bovine kidney to accommodate these new conditions of use. This approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the new injection site (posterior aspect of the ear where it attaches to the head [base of the ear]) and new indication (treatment of BRD in lactating dairy cattle) for which this supplement is approved.

21CFR 522.315 & 556.113

NADA Number: 140-338

Trade Name: Naxcel® Sterile Powder
Ingredients: Ceftiofur sodium
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for the establishment of a 4-day pre-slaughter withdrawal period in cattle.

21CFR 522.313c

NADA Number: 140-890

Trade Name: Excenel® RTU Sterile Powder
Ingredients: Ceftiofur hydrochloride
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for the establishment of a 3-day pre-slaughter withdrawal period in cattle.

21CFR 522.313b

NADA Number: 141-238

Trade Name: Spectramast® LC Sterile Suspension
Ingredients: Ceftiofur hydrochloride
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for the establishment of a 2-day pre-slaughter withdrawal period in cattle.

21CFR 526.313

NADA Number: 141-239

Trade Name: Spectramast® DC Sterile Suspension
Ingredients: Ceftiofur hydrochloride
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for the establishment of a 16-day pre-slaughter withdrawal period in cattle.

21CFR 526.313

NADA Number: 034-478

Trade Name: Salix® Injection 5%
Ingredients: Furosemide
Sponsor: Intervet Inc.
Approval Date: June 20, 2006

This application provides for revised food safety warning on labeling.

21CFR 522.1010

NADA Number: 100-703

Trade Name: Carbocaine®-V Sterile Aqueous Solution
Ingredients: Mepivacaine hydrochloride
Sponsor: Pharmacia & Upjohn Co.
Approval Date: June 2, 2006

This application provides for revised food safety labeling.

21CFR 522.1372

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-292

Trade Name: Iversol Liquid for Horses
Ingredients: Ivermectin
Sponsor: Med-Pharmex, Inc.
Approval Date: May 30, 2006

This application provides for revised food safety warning on labeling and indications to conform to the pioneer product's labeling.

21CFR 520.1195

ANADA Number: 200-316

Trade Name: Clintabs®
Ingredients: Clindamycin hydrochloride
Sponsor: Virbac AH, Inc.
Approval Date: June 2, 2006

This application provides for an expanded dose range and revised wording of indications for the treatment of certain bacterial diseases.

21CFR 520.446

ANADA Number: 200-291

Trade Name: Clinsol®
Ingredients: Clindamycin hydrochloride
Sponsor: Virbac AH, Inc.
Approval Date: June 12, 2006

This application provides for an expanded dose range and revised wording of indications for the treatment of certain bacterial diseases.

21CFR 520.447

Correction of Patent Information

NADA Number: 141-063

Patent Numbers: 5,082,862 Expiration Dates: August 29, 2010

Notice(s)

The Food and Drug Administration (FDA) is announcing the withdrawal of a compliance policy guide (CPG) that was issued on March 19, 1991. In a notice published in the Federal Register of July 30, 1992 (57 FR 33729), FDA announced the availability of a revised CPG 7125.35 entitled ``Human-Labeled Drugs Distributed and Used in Animal Medicine." The CPG is being withdrawn because it is obsolete. This CPG explained how FDA would exercise its enforcement discretion with respect to the distribution and use of human-labeled drug products for use in animals.

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) was signed into law on October 22, 1994. AMDUCA allows veterinarians to prescribe extralabel uses of approved animal drugs and approved human drugs for animals under certain conditions. An extralabel use must be by or on the order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and must be in conformance with the implementing regulations published in part 530 (21 CFR part 530). A list of drugs specifically prohibited from extralabel use in animals is in Sec. 530.41. With the enactment of AMDUCA and the issuance of implementing regulations, FDA is withdrawing CPG 7125.35 because it is obsolete. On September 24, 1998, a CPG section 615.100 entitled ``Extralabel Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)" was withdrawn for the same reason (63 FR 51074).

The withdrawal is effective July 7, 2006.

For further information contact: Diane D. Jeang, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6833.

The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled ``Sec. 616.100 Streptomycin Residues in Cattle Tissues (CPG 7125.22)." This CPG is obsolete. FDA issued the CGP entitled ``Sec. 616.100 Streptomycin Residues in Cattle Tissues (CPG 7125.22)" on October 1, 1980. The CPG was issued because there were no published tolerances for residues of streptomycin in cattle tissue and the available data supported an action level of 2 parts per million (ppm) streptomycin/dihydrostreptomycin residues in cattle kidney tissue. The U.S. Department of Agriculture, Food Safety Quality Service (now known as the Food Safety Inspection Service) agreed to report any detectable residues in other edible tissue and to report to FDA only those cattle kidney tissue reports where the streptomycin residue was 2 ppm or more. Since issuing this CPG, FDA has established tolerances for dihydrostreptomycin (59 FR 41976, August 16, 1994) and streptomycin (58 FR 47210, September 8, 1993). Tolerances are established for residues of dihydrostreptomycin in uncooked, edible tissues of cattle and swine of 2.0 ppm in kidney and 0.5 ppm in other tissues, and 0.125 ppm in milk. (See 21 CFR 556.200.) Tolerances are established for residues of streptomycin in uncooked, edible tissues of chickens, swine, and calves of 2.0 ppm in kidney, and 0.5 ppm in other tissues. (See 21 CFR 556.610.) FDA is withdrawing CPG 7125.22, in its entirety, to eliminate obsolete compliance policy.

The withdrawal is effective July 7, 2006.

For further information contact: Diane D. Jeang, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6833.